

CERTIFICATE OF MAILING

I hereby certify that this *Information Disclosure Statement* is being deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on this, the 5<sup>th</sup> day of April, 2004.

Suzanne Colón  
SIGNATURE

Suzanne Colón  
PRINTED NAME OF PERSON SIGNING CERTIFICATE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Byrd, et al.

) Examiner: Unknown

Serial No.: Unknown

10/700,264

) Art Unit: Unknown

Filed: November 3, 2003

) Attorney Docket: 18525/04052

For: **CRYOGENIC ABNORMALITIES THAT ARE PREDICTIVE OF RESPONSE TO THERAPY FOR CHRONIC LYMPHOCYTIC LEUKEMIA**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith are the following:

1. Information Disclosure Statement;
2. Form PTO-1449 (2 pages);
3. Twelve (12) References; and
4. Return Receipt Postcard.

It is believed that no further fee is required relating to the filing of this Information Disclosure Statement. If this is not the case, the Patent Office is hereby authorized to charge any related fee to Deposit Account No. 03-0172. A duplicate copy of this sheet is attached.

Respectfully submitted,

Date: April 5, 2004

By: Diane H. Dobrea

Diane H. Dobrea, Reg. No. 48,578  
216/622-8485



CERTIFICATE OF MAILING

I hereby certify that this INFORMATION DISCLOSURE STATEMENT is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5<sup>th</sup> day of April, 2004.

Signed

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                                     |   |                              |
|-------------------------------------|---|------------------------------|
| In re Application of : Byrd, et al. | ) | Examiner: Unknown            |
|                                     | ) |                              |
| Serial No.: Unknown                 | ) | Art Unit: Unknown            |
|                                     | ) |                              |
| Filed: November 3, 2003             | ) |                              |
|                                     | ) |                              |
|                                     | ) | Attorney Docket: 18525/04052 |

For: **CRYOGENIC ABNORMALITIES THAT ARE PREDICTIVE OF RESPONSE TO THERAPY FOR CHRONIC LYMPHOCYTIC LEUKEMIA**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

This information disclosure statement is being filed before the mailing of a first Office Action on the merits. Applicants wish to disclose the following information:

**REFERENCES**

- ☒ The Applicants wish to make of record the references listed on the attached Form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ Listed on the attached PTO form 1449 is information known to persons substantively involved in the preparation of the application identified above, and is not a representation that more pertinent information does not exist.

- ☒ The identification of any information herein is not intended to be, and should not be understood as being, an admission that such information, in fact, constitutes "prior art" within the meaning of applicable law. The "prior art" status of any information is a matter to be resolved during prosecution.

### **CERTIFICATION**


- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.
- ☒ This information disclosure statement is being filed within **three months** of the filing of the application and/or prior to a first Office Action on the merits.

### **DEPOSIT ACCOUNT**

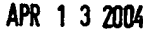
- ☐ A check is attached in the amount of \$ \_\_\_\_\_ required under 37 § 1.17(p).
- ☒ It is not believed that any fee is required relating to the filing of this information disclosure statement. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 03-0172**.

Respectfully submitted,

Date: April 5, 2004

By: 

Diane H. Dobrea, Reg. No. 48,578  
216-622-8485



Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 949/PTO

**(Use as many sheets as necessary)**

Sheet 1 of 2

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | Unknown          |
| Filing Date            | November 3, 2003 |
| First Named Inventor   | Byrd, et al.     |
| Art Unit               | Unknown          |
| Examiner Name          | Unknown          |
| Attorney Docket Number | 18525/04052      |

[illegible][illegible]

**Examiner  
Signature**

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND**

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

APR 13 2004

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 746

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number Unknown

Filing Date November 3, 2003

First Named Inventor Byrd, et al.

Art Unit Unknown

Examiner Name Unknown

Attorney Docket Number 18525/04052

Sheet 2

of

2

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    | AA                    | BYRD, ET AL., "Interphase Cytogenetic Abnormalities in Chronic Lymphocytic Leukemia May Predict Response to Rituximab." Cancer Research 63 (January 1, 2003), pp. 36-38.  |                |
|                    | AB                    | DOHNER, ET AL., "Genomic Aberrations and Survival in Chronic Lymphocytic Leukemia." The New England Journal of Medicine (December 28, 2000) pp. 1910-1916.  |                |
|                    | AC                    | CHESON, ET AL., "National Cancer Institute - Sponsored Working Group Guidelines for Chronic Lymphocytic Leukemia: Revised Guidelines for Diagnosis and Treatment." Blood, Vol. 87, No. 12 (June 15, 1996) pp. 4990-4997.  |                |
|                    | AD                    | BYRD, ET AL., "Rituximab Using a Thrice Weekly Dosing Schedule in B-Cell Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma Demonstrates Clinical Activity and   |                |
|                    |                       | Acceptable Toxicity." Journal of Clinical Oncology, Vol. 19, No. 8 (April 15, 2001) pp. 2153-2164.  |                |
|                    | AE                    | KAY, ET AL., "Chronic Lymphocytic Leukemia." Hematology (2002) pp. 193-213.   |                |
|                    | AF                    | HITT, EMMA., "New Directions in Hematologic Malignancies; An Interview with John C. Byrd, MD." Medscape from WbMD, pp.1-2.  |                |
|                    | AG                    | LOZANSKI, ET AL., "Alemtuzumab is an Effective Therapy for Chronic Lymphocytic Leukemia with P53 Mutations and Deletions." Abstract, Blood (01/15/04).  |                |
|                    |                       |   |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.